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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,934	07/14/2003	Laurens Nicolaas Sierkstra	4322.230-US	6607
25908	7590	08/25/2005	EXAMINER	
NOVOZYMES NORTH AMERICA, INC. 500 FIFTH AVENUE SUITE 1600 NEW YORK, NY 10110			MOORE, WILLIAM W	
			ART UNIT	PAPER NUMBER
			1656	

DATE MAILED: 08/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/618,934	SIERKSTRA ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	William W. Moore	1652

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

#### Period for Reply

#### A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 06 August 2004.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 34-87 is/are pending in the application.
- 4a) Of the above claim(s) 42-45, 52-55, 60-63, 68-71, 76-79 and 84-87 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 34-41, 46-51, 56-59, 64-67, 72-27 and 80-83 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. 08/642,987.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>20030714 &amp; 20040806</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

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## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

1. Claims 34-41, 46-51, 56-59, 64-67, 72-75, and 80-83 drawn to subtilases modified by a first amino acid substitution at one of the subtilisin BPN'-correspondent positions 136, 167 170, 171, and 194, and to detergent compositions comprising same, classified, *inter alia*, in class 435, subclass 220.
2. Claims 42-45, 52-55, 60-63, 68-71, 76-79, and 84-87, drawn to nucleic acid sequences encoding subtilases modified by an amino acid substitution at one or more of the subtilisin BPN'-correspondent amino acid positions 136, 167 170, 171, and 194, to vectors and microbial host cells comprising said nucleic acid sequences, and to methods of making an encoded, modified, subtilase utilizing nucleic acid sequences, classified, *inter alia*, in class 435, subclass 69.1.

Inventions of Groups 1 and Groups 2 are unrelated, respectively, one to another.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are independent chemical entities and require separate searches in the patent and non-patent literature.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. Elias J. Lambiris on 10 June 2005 a provisional election was made **with** traverse to prosecute the invention of Group 1 comprising claims 34-41, 46-51, 56-59, 64-67, 72-75, and 80-83. Affirmation of this election must be made by applicant in replying to this Office action. Claims 42-45, 52-55, 60-63, 68-71, 76-79 and 84-87 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

### *Priority*

Acknowledgment is made of applicant's claim under 35 U.S.C. §§ 119(a)-(d) for the priority of Danish Patent Applications 0519/95 and 0421/96, and the European Patent Application 95-201161. The certified copies were filed on 6 May 1996 in Application serial No. 08/642,987.

*Information Disclosure Statement*

Applicant's Information Disclosure Statement filed 6 August 2004 is hereby acknowledged.

*Objection to the Specification: Sequence Rules Compliance*

The Sequence Listing filed with the application provides the nucleic acid sequences of SEQ IDs NOs:1-6 in printed form. The computer readable form was transferred from the parent Application No. 08/642,987 at Applicant's request. The specification fails to comply with 37 CFR 1.821, however, by providing sequence listings in both printed and computer-readable form for the 35 subtilase amino acid sequences compared in Figure 1. These 35 sequences are disclosures encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR §§1.821(a)(1) and (a)(2). Figure 1 must also be amended to include the new sequence designators where 37 CFR §§1.821(b), (c) and (d) require that descriptions of defined amino acid sequences within the specification be accompanied by a designation properly stated as "**SEQ ID NO:n**". Failure to comply with the requirements in response to this communication will result in ABANDONMENT of the application under 37 CFR §1.821(g).

*Claim Objections*

Claims 34, 46 and 56 are objected to because they fail to state a proper Markush format in describing their subject matters. Specifically, claim 34 improperly states the word "and" between clauses (a) and (b) of the claim but fails to properly include the word "and" between clauses (c) and (d). Claims 46 and 56 fail to include the word "and" between clauses (a) and (b) of the claim.

*Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 34-41, 46-51, 56-59, 64-67, 72-75 and 80-83 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 34, 46, 56, 64, 72, and 80 are rejected as indefinite because none states a sequence identifier at the close of their terminal clause with which the referenced sequence can be identified. Claims 35-41, 47-51, 57-59, 65-67, 73-75 and 81-83 are included in this rejection because none of these claims resolves the ambiguity of the claim from which it depends.

#### *Double Patenting*

The following double patenting rejections are required because, while a few US Patents and pending applications include a co-inventor within the inventive entity named for the instant application, all cited US Patents and pending applications are commonly-assigned and also because, as noted above in the rejection of claims herein under 35 U.S.C. § 112, second paragraph, the failure to cite a sequence designation in the independent claims admits further amino acid sequence modifications within the embrace of the claims.

#### Non-Provisional Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 34, 35, 37, 39-41, 46, 48-51, 56-59, and 64 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over

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claims 1, 7, 16, 30-39 and 42-49 of U.S. Patent No. 5,482,849. Although the conflicting claims are not identical, they are not patentably distinct from each other because modified subtilases and detergent compositions comprising same of claims 34, 35, 37, 39-41, 46, 48-51, 56-59, and 64 herein comprise a Y167F or Y171F substitution wherein a Y167F substitution is further combined with one or more of the K27R, H120D and K235L substitutions of the modified subtilisins BPN', 309, 147, and PB92, see claims 42-44, of the patented claims and detergent compositions comprising same.

Claims 34, 35, 37, and 39-41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 5, 11, 12, 20, 34-43, and 46-48 of U.S. Patent No. 5,631,217. Although the conflicting claims are not identical, they are not patentably distinct from each other because modified subtilases and detergent compositions comprising same of claims 34, 35, 37, and 39-41 herein comprise a Y167W, Y167F or Y171F substitution wherein a Y167F substitution is further combined with one or more of the K27R, H120D and K235L substitutions of the modified subtilisins BPN', 309, 147, and PB92, see claims 42-44, of the patented claims and detergent compositions comprising same.

Claims 34, 39, and 41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 34, 39, 56, 90, 97, 111, and 121-123 of U.S. Patent No. 5,741,694. Although the conflicting claims are not identical, they are not patentably distinct from each other because modified subtilases and detergent compositions comprising same of claims 34, 39, and 41 herein comprise amino acid substitutions at positions 57, 120, 194, and 235 embraced by the generic substitutions at positions 57, 120, 194, and 235 of the modified subtilisins BPN', 309 and 147 and detergent compositions comprising same of the patented claims.

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Claims 34-36 and 38-41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28, 30 and 31 of U.S. Patent No. 5,837,517. Although the conflicting claims are not identical, they are not patentably distinct from each other because modified subtilases and detergent compositions comprising same of claims 34-36 and 38-41 herein comprise one or more of the 167V, 170I, or 194P substitutions of modified subtilases of the patented claims that further comprise at least one ancillary substitution or deletion at one or more of the positions 36, 57, 76, 97, 104, 120, 206, 218, 222, and 235 and detergent compositions comprising same.

Claims 34, 37, 41, 46, 48, 51, 56, and 59 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,110,884. Although the conflicting claims are not identical, they are not patentably distinct from each other because modified subtilisins 309 and 147 and detergent compositions comprising same of claims 34, 37, 41, 46, 48, 51, 56, and 59 herein comprise a Y171F substitution of the modified subtilisins 309 and 147 and detergent compositions comprising same of the patented claims.

Claims 34-41, 46, 48-51, 56-59, 64-67, 72-75, and 80-83 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,190,900. Although the conflicting claims are not identical, they are not patentably distinct from each other because modified subtilases and detergent compositions comprising same of claims 34-41, 46, 48-51, 56-59, 64-67, 72-75, and 80-83 herein comprise one or more of the more hydrophobic amino acid substitutions of modified subtilases of the patented claims that also comprise at least one ancillary substitution or deletion at one or more of the positions 36, 57, 76, 97, 104, 120, 206, 218, 222, and 235 and detergent compositions comprising same.

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Claims 34, 37, 41, 46, 48, 51, 56, and 59 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,110,884. Although the conflicting claims are not identical, they are not patentably distinct from each other because modified subtilisins 309 and 147 and detergent compositions comprising same of claims 34, 37, 41, 46, 48, 51, 56, and 59 herein comprise a Y171F substitution of the modified subtilisins 309 and 147 and detergent compositions comprising same of the patented claims.

Claims 34-36 and 38-41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3, 4 and 7-14 of U.S. Patent No. 6,555,355. Although the conflicting claims are not identical, they are not patentably distinct from each other because the modified subtilases and detergent compositions comprising same of claims 34-36 and 38-41 herein embrace one or more generic substitutions at positions 167 and 170 and/or a A194P substitution of the patented claims 7 and 8 that may further comprise at least one ancillary modification or mutation at one or more of the positions 36, 57, 76, 97, 104, 120, 206, 218, 222, and 235 and detergent compositions comprising same.

Claims 34-36 and 38-40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3-8 of U.S. Patent No. 6,558,938. Although the conflicting claims are not identical, they are not patentably distinct from each other because modified subtilases of claims 34-36 and 38-40 herein comprise one or more generic substitutions at positions 167 and 170 and/or a A194P substitution of modified subtilases of the patented claims that further comprise at least one ancillary substitution or deletion at one or more of the positions 36, 57, 76, 97, 104, 120, 206, 218, 222, and 235.

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Claims 34-36 and 38-40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17-19, 21, 38-41, 43, 66-68 and 70 of U.S. Patent No. 6,605,458. Although the conflicting claims are not identical, they are not patentably distinct from each other because modified subtilases of claims 34-36 and 38-40 herein comprise one or more generic substitutions at positions 167 and 170 and/or a A194P substitution of modified subtilases of the patented claims that further comprise at least one ancillary substitution or deletion at one or more of the positions 36, 57, 76, 97, 104, 120, 206, 218, 222, and 235.

Claims 34-36 and 39-41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 8, 10, 14, 15, 21, 23, and 29-33 of U.S. Patent No. 6,682,924. Although the conflicting claims are not identical, they are not patentably distinct from each other because modified subtilases, and detergent compositions comprising same of claims 34-36 and 39-41 herein comprise one or more of the 167V, 167M, 167P, 167W, 170I, and 170M substitutions of modified subtilases of the patented claims that further comprise at least one ancillary substitution or deletion at one or more of the positions 36, 57, 76, 97, 104, 120, 206, 218, 222, and 235, and detergent compositions comprising same.

Claims 34-36 and 38-40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10-15, 35-40, 60-65, 86-91, 111-116, 136-141, 161-166, 186-191, and 211-216 of U.S. Patent No. 6,773,907. Although the conflicting claims are not identical, they are not patentably distinct from each other because modified subtilases of claims 34-36 and 38-40 herein comprise one or more generic substitutions at positions 167 and 170 and/or a A194P substitution of modified subtilases of the patented claims that further comprise at least

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one ancillary substitution or deletion at one or more of the positions 36, 57, 76, 97, 104, 120, 206, 218, 222, and 235.

Claims 34-36 and 39-41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8, 9, 22, and 23 of U.S. Patent No. 6,777,218. Although the conflicting claims are not identical, they are not patentably distinct from each other because modified subtilases and detergent compositions comprising same of claims 34-36 and 39-41 herein comprise one or more of the generic substitutions at positions 167 and 170 of modified subtilases of the patented claims that further comprise at least one ancillary substitution or deletion at one or more of the positions 36, 57, 76, 97, 104, 120, 206, 218, 222, and 235 and detergent compositions comprising same.

Claims 34-36 and 38-40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9-14, 33-38, 57-62, 81-86, 105-110, 129-134, 153-158, and 177-182 of U.S. Patent No. 6,780,629. Although the conflicting claims are not identical, they are not patentably distinct from each other because modified subtilases and detergent compositions comprising same of claims 34-36 and 38-40 herein comprise one or more generic substitutions at positions 167 and 170 and/or a A194P substitution of modified subtilases of the patented claims that further comprise at least one ancillary substitution or deletion at one or more of the positions 36, 57, 76, 97, 104, 120, 206, 218, 222, and 235 and detergent compositions comprising same.

Claims 34, 36 and 38-41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6 and 7 of U.S. Patent No. 6,808,913. Although the conflicting claims are not identical, they are not patentably distinct from each other because modified subtilases and detergent

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compositions comprising same of claims 34, 36 and 38-41 herein comprise one or more generic substitutions at positions 170 and 194 of a modified subtilisin 309 of the patented claims that further comprise at least one ancillary modification or mutation at one or more of the positions 222 and 235 and detergent compositions comprising same.

Claims 34-36 and 38-41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 16-22, 25 and 26 of U.S. Patent No. 6,893,855. Although the conflicting claims are not identical, they are not patentably distinct from each other because modified subtilases and detergent compositions comprising same of claims 34-36 and 38-41 herein comprise one or more generic substitutions at positions 167 and 170 and/or a A194P substitution of modified subtilases of the patented claims that further comprise at least one ancillary modification or mutation at one or more of the positions 27, 36, 76, 97, 104, 120, 206, 218, 222, 235 and 274 and detergent compositions comprising same.

Claims 34-36 and 38-41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5, 8-15, 18 and 21-28 of U.S. Patent No. 6,921,657. Although the conflicting claims are not identical, they are not patentably distinct from each other because modified subtilases and detergent compositions comprising same of claims 34-36 and 38-41 herein comprise one or more generic substitutions at positions 167 and 170 and/or a A194P substitution of modified subtilases of the patented claims that further comprise at least one ancillary modification or mutation at one or more of the positions 27, 36, 76, 97, 104, 120, 206, 218, 222, 235 and 274 and detergent compositions comprising same.

B. Provisional Double Patenting

The following, several, rejections are provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented.

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Claims 34-36 and 39-40 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 52-54, 60, 61, and 74-78 of copending application serial No. 09/931,701. Although the conflicting claims are not identical, they are not patentably distinct from each other because modified subtilases of claims 34-36 and 38-40 herein comprise one or more of the generic substitutions at positions 167 and 170, as well as the A194P substitution, of modified subtilases of the copending application's claims that further comprise at least one ancillary substitution or deletion at one or more of the positions 36, 57, 76, 97, 104, 120, 206, 218, 222, 235, and 274 and detergent compositions comprising same.

Claims 34-41, 46, 48-51, 56-59, and 64-67 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 38-51, 56, 63-65, 69, 75-71, and 80-93 of copending application serial No. 09/948,080. Although the conflicting claims are not identical, they are not patentably distinct from each other because modified subtilases of claims 34-41, 46, 48-51, 56-59, and 64-67 herein comprise each of the specific substitutions at positions 167, 170, 171, and a generic substitution at position 194 of modified subtilases of the copending application's claims that further comprise at least one ancillary substitution or deletion at one or more of the positions 36, 57, 76, 97, 104, 120, 206, 218, 222, and 235 and detergent compositions comprising same.

Claims 34, 36, 41, 46, 47, 51, 56, and 59 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 78, 82-85, 87, 89, 90, 92, 120 and 122 of copending application serial No. 09/957,806. Although the conflicting claims are not identical, they are not patentably distinct from each other because modified subtilases of claims 34, 36, 41, 46, 47, 51, 56, and 59 and detergent compositions comprising same herein comprise several

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among the specific substitutions recited in the claims herein at positions 136 and 170 of generic modified subtilases of the copending application's claims and detergent compositions comprising same.

Claims 34, 36, 38, 41, 46-51 and 56-59 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 8, 19, 28, 41, 44, 45, 55, and 74 of copending application serial No. 10/314,191. Although the conflicting claims are not identical, they are not patentably distinct from each other because modified subtilases of claims 34, 36, 38-41, 46, 48-51, 56-59, and 64-67 herein, and detergent compositions comprising same, comprise one or more of the generic substitutions at positions 136, 167, 170, and 194 of modified subtilisins 309 and 147 of the copending application's claims that further comprise at least one ancillary substitution or deletion at one or more of the positions 27, 76, 101, and 206, and detergent compositions comprising same.

Claims 34-36 and 38-41 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 45, 48, and 51 of copending application serial No. 10/403,105. Although the conflicting claims are not identical, they are not patentably distinct from each other because modified subtilases of claims 34-36 and 38-41 herein and detergent compositions comprising same, comprise one or more of the generic substitutions at positions 167 and 170, as well as the A194P substitution, of modified subtilases of the copending application's claims that further comprise at least one ancillary substitution or deletion at one or more of the positions 27, 36, 57, 76, 97, 101, 104, 206, and 222 and detergent compositions comprising same.

Claims 34, 36, 38-41, 46, 48-51, 56-59, and 64-67 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being

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unpatentable over claims 1, 2 and 4-9 of copending application serial No. 10/699,394. Although the conflicting claims are not identical, they are not patentably distinct from each other because modified subtilases of claims 34, 36, 38-41, 46, 48-51, 56-59, and 64-67 herein, and detergent compositions comprising same, comprise one or more of the generic substitutions at position 170, as well as the Y171C and A194 substitutions, of modified subtilases, particularly I-S2 subtilases such as subtilisins 309, 147 and PB92, of the copending application's claims that further comprise at least one ancillary substitution or deletion at one or more of the positions 36, 57, 76, 97, 104, 120, 206, 218, 222, and 235 and detergent compositions comprising same.

Claims 34, 36, 37, and 40 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 19 of copending application serial No. 10/786,850. Although the conflicting claims are not identical, they are not patentably distinct from each other because modified subtilases of claims 34-36, 39, and 40 herein comprise one or more of the generic substitutions at positions 170 and 171 of modified subtilases of the copending application's claim that further comprise at least one ancillary substitution or deletion at position 218.

Claims 34-36, 39, and 40 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 70-73 of copending application serial No. 10/884,325. Although the conflicting claims are not identical, they are not patentably distinct from each other because modified subtilases of claims 34-36, 39, and 40 herein comprise one or more of the generic substitutions at positions 167, 170, and 194 of modified subtilases of the copending application's claims that further comprise at least one ancillary substitution or deletion at one or more of the positions 27, 36, 76, 97, 101, 104, 120, 123, 206, 218, 222, and 235 and detergent compositions comprising same.

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Claims 34, 36, and 39-41 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 25, 28, 29, and 32-34 of copending application serial No. 10/896,177. Although the conflicting claims are not identical, they are not patentably distinct from each other because modified S-I and S-II subtilases of claims 34, 36, and 39-41 herein comprise one or more of the generic substitutions at position 170 of a modified subtilisin 309 of the copending application's claims that further comprise at least one ancillary substitution at one or more of the positions 218 and 222 and detergent compositions comprising same.

Again, these several rejections are provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented. As noted above, a timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

#### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 34, 35, 37, 39-41, 46, 48, 51, 56, 59, 64 and 67 are rejected under 35 U.S.C. § 102(e) as being anticipated by Branner et al., US 5,482,849 and US 5,631,217, both made of record with Applicant's Information disclosure Statement filed 14 July 2003.

Branner et al., '849 and '217, share an effective US filing date of December 1991 and both disclose modified subtilisins BPN', 309, 147 and PB92 having phenylalanine

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substitutions at the subtilisin BPN'-correspondent positions Y167 and Y171 wherein the Y167F substitution is combined with one or more of the further substitutions K27R, H120D, and K235L. See claims 1, 7, 16, 30-39 and 42-49.

Claims 34, 38 and 41 are rejected under 35 U.S.C. §102(e) as being anticipated by Hastrup et al., U.S. Patent No. 5,741,694, made of record with Applicant's Information disclosure Statement filed 14 July 2003.

Hastrup et al., '288, have an effective U.S. filing date of January 1989 and disclose subtilisin variants having generic amino acid substitutions at the subtilisin BPN'-correspondent position 194.

Claims 34, 35, 41, 46, 48, 51, 56, and 59 are rejected under 35 U.S.C. § 102(e) as being anticipated by Rasmussen et al., US 6,110,884, made of record herewith.

Rasmussen et al. have an effective US filing date of December 1995 and disclose modified subtilisins 309 and 147 comprising a Y171F substitution as well as detergent compositions comprising same. See claims 1-8.

Claims are 34, 35, 41, 46, 48, 51, 56, 59, 72, 75, 80, and 83 are rejected under 35 U.S.C. §102(b) as being anticipated by Branner et al., WO 91/00345, and under 35 U.S.C. §102(e) as being anticipated by Aaslyng et al., U.S. Patents Nos. 5,665,587 and 6,197,567, all of record with Applicant's Information disclosure Statement filed 14 July 2003.

The disclosures of Branner et al., '345, and both of Aaslyng et al., '587 and '657, are identical and the US patents to Aaslyng et al. have effective U.S. filing dates of April 1990. All identically disclose modified subtilisins BPN', Carlsberg, 309, and 147 having E136Q, Y167V, and Y171T amino acid substitutions at the subtilisin BPN'-correspondent positions 136, 167, 170, and 171. See Table 1 at cols. 9-18, and col. 23, lines 48-54 of the '567 patent.

Claims 34-37 and 41 are rejected under 35 U.S.C. §102(b) as being anticipated by Wells et al., EP 0251466, and under U.S.C. §102(e) as being anticipated by Bott et al., U.S. Patent No. 5,700,676, both made of record with Applicant's Information disclosure Statement filed 14 July 2003.

Wells et al., '466, and Bott et al., '676, are identical disclosures where Bott et al., '676, have an effective U.S. filing date of April 1987. Both identically disclose subtilisin

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variants having generic amino acid substitutions at the subtilisin BPN'-correspondent position 167 and 170, and the substitution Y171F. See claims 1, 2, 5, 7, 8, 23, and 40.

Claims 34, 35, 37, 41, 46-48, 51, 56, 59, 72 and 75 are rejected under 35 U.S.C. §102(b) as being anticipated by Casteleijn et al., EP 0405901, made of record with Applicant's Information disclosure Statement filed 14 July 2003.

Casteleijn et al. disclose modified subtilisins BPN', 309, and 147 having a Gln substitution at the subtilisin BPN'-correspondent position 136, a Val substitution at the subtilisin BPN'-correspondent position 167, and the substitution Y171T at the subtilisin BPN'-correspondent position 171, as well as detergent compositions comprising same.

Claims are 34, 35, 38, 41, 46-48; 51, 56, 59, 64, 67, 72, 75, 80, and 83 are rejected under 35 U.S.C. §102(b) as being anticipated by Branner et al., WO 91/00345, and under 35 U.S.C. §102(e) as being anticipated by Åaslyng et al., U.S. Patents Nos. 5,665,587 and 6,197,567, all of record with Applicant's Information disclosure Statement filed 14 July 2003.

The disclosures of Branner et al. and both of Åaslyng et al. are identical and both US patents to Åaslyng et al. have effective U.S. filing dates of April 1990. All identically disclose modified subtilisins BPN', Carlsberg, 309, 147 and PB92 that have a Gln substitution at the subtilisin BPN'-correspondent position 136, a Val substitution at the subtilisin BPN'-correspondent position 167, a Thr substitution at the subtilisin BPN'-correspondent position 171 and a generic substitution at the subtilisin BPN'-correspondent position 194, and detergent compositions comprising same. See, e.g., cols. 19 and 20 of the '587 patent.

Claims 34, 35, 41, 46-48, 51, 56, 59 are rejected under 35 U.S.C. §102(b) as being anticipated by Branner et al., WO 92/11357, made of record with Applicant's Information disclosure Statement filed 14 July 2003.

Branner et al., '357, disclose modified subtilisins 309 and 147 that have a Gln substitution at the subtilisin BPN'-correspondent position 136, a Val substitution at the subtilisin BPN'-correspondent position 167, a Thr substitution at the subtilisin BPN'-correspondent position 171, and detergent compositions comprising same.

Claims 34, 38 and 41 are rejected under 35 U.S.C. §102(b) as being anticipated by Christianson et al., WO 92/21760 and under 35 U.S.C. §102(e) as being anticipated by

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Christianson et al. U.S. Patents Nos. 5,500,364 and 5,340,735, made of record with Applicant's Information Disclosure Statement filed 14 July 2003.

The disclosures of both patents to Christianson et al. are identical, both share an effective US filing date of May 1991, and both identically disclose a modified subtilisin PB92 having a Pro amino acid substitution at the subtilisin BPN'-correspondent position 194 and detergent compositions comprising same. See the A188P substitution of Table 2, where position 188 corresponds to the subtilisin BPN' position 194.

Claims 34, 38 and 41 are rejected under 35 U.S.C. §102(e) as being anticipated by Maurer et al., U.S. Patent No. 5,801,039, made of record with Applicant's Information disclosure Statement filed 14 July 2003.

Maurer et al., '039, have an effective U.S. filing date of February 1994 and disclose a modified subtilisin having a Pro amino acid substitution at the subtilisin BPN'-correspondent position 194 and detergent compositions comprising same. This is the A188P substitution, where position 188 corresponds to the subtilisin BPN' position 194. See col. 2, lines 30-33.

Claims 34, 38 and 41 are rejected under 35 U.S.C. §102(e) as being anticipated by Maurer et al., U.S. Patent No. 6,197,589, made of record with Applicant's Information disclosure Statement filed 14 July 2003.

Maurer et al., '589, have an effective U.S. filing date of October 1994 and disclose a modified subtilisin having a Pro amino acid substitution at the subtilisin BPN'-correspondent position 194 and detergent compositions comprising same. This is the A188P substitution, where position 188 corresponds to the subtilisin BPN' position 194. See col. 2, lines 33-35.

### *Conclusion*

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is

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571.272.0933 and whose FAX number is 571.273.0933. The examiner can normally be reached Monday through Friday between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisory Primary Examiner, Dr. Kathleen Kerr, can be reached at 571.272.0931. The official FAX number for all communications for the organization where this application or proceeding is assigned is 571.273.8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571.272.1600.

William W. Moore  
19 August 2005



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